UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

PATRICIA A. KING,	*	
PLAINTIFF	*	
	*	
V.	*	CIVIL ACTION NO:11-cv-001270-RWT
	*	
PFIZER PHARMACEUTICAL COMPANY, INC.,	*	
	*	
DEFENDANT	*	

RESPONSE TO MOTION TO DISMISS

While inartfully stated, Plaintiff's complaint does state sufficient facts to withstand Defendant's Motion to Dismiss. Plaintiff's failure to state in detail the actions of Defendant that resulted in her injury and Defendant's liability for that injury should not preclude the Court from allowing Plaintiff an opportunity to more fully outline the factual and legal basis for her claim.

Under Maryland Rule 2-501(a), summary judgment is only appropriate where there is no dispute of material fact and the moving party is entitled to judgment as a matter of law. Therefore a motion for summary judgment should be denied where the opposing party has shown that "there is a genuine dispute as to a material fact by proffering facts which would be admissible as evidence." Beatty v. Trailmasters Products, Inc., 330 Md. 726, 737 (1993). "A material fact is a fact

the resolution of which will somehow affect the outcome of the case." Carter v. Aramark Sports and Entertainment, 153 Md.App. 210, 224 (2003) (quoting Sterling v. Johns Hopkins Hosp., 145 Md.App. 161, 167 (2002), cert. denied, 371 Md. 264 (2002)).

"When ruling on a motion for summary judgment, a court must view the facts, including all inferences drawn therefrom, in the light most favorable to the opposing party." Carter, 153 Md.App. at 224, (citing Sterling, 145 Md. App. at 168, quoting Jones v. Mid-Atlantic Funding Co., 362 Md. 661, 676 (2001)). "The moving party bears the burden of establishing the absence of a genuine issue of material fact." Carter, 153 Md.App. at 224, (citing Sterling, 145 Md.App. at 168, citing Adickes v. S.H. Kress & Co., 398 U.S. 144, 157 (1970)), therefore the Defendant must show the absence of disputed facts. Furthermore, the standard is such that the trial court is not to draw inferences in favor of the moving party. Rather, if the facts are undisputed, but these facts "are susceptible of more than one permissible inference, the choice between those inferences should not be made as a matter of law." Carter, 153 Md.App. at 225, (citing, Porter v. General Boiler Casing Co., 284 Md. 402, 413 (1979), quoting Fenwick Motor Co. v. Fenwick, 258 Md. 134, 138 (1970)).

I. Issues of Material Fact

Plaintiff's complaint, while not explicitly stated, inherently alleges a failure to warn by Defendant of the dangers of taking Lipitor. Defendant's warning was

inadequate regarding the side effects of Lipitor. Following the onset of the extreme muscle pain and weakness, Plaintiff sought information that she had not had access to at a time when its importance could be evaluated. Her conversations with her treating physician included questions about leg pain and its relationship to the side effects of Lipitor but she was assured that such side effects were extremely rare and not preceded by mild or moderate pain.

In addition Defendant's promotion, marketing, and advertising to physicians of Lipitor outside the FDA guidelines (See Ex. A, B, C, D, E), undermine the role of the "learned intermediary" and Defendant's reliance on it warning labels for protection as a matter of law.

II. The Lipitor Warning Label(s) Were Not Adequate as a Matter of Law

In March 2009, the U.S. Supreme Court held in Wyeth v. Levine, 555 U. S. _____ (2009), that approval by the Food and Drug Administration (FDA) of warnings on the drug's label do not provide Wyeth (the pharmaceutical manufacturer) with a complete defense to tort claims. The decision stated that "[i]n keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market,[11] and manufacturers have superior access to information about their

[1] "In 1955, the same year that the agency approved Wyeth's Phenergan application, an FDA advisory committee issued a report finding "conclusively" that "the budget and staff of the Food and Drug Administration are inadequate to permit the discharge of its existing responsibilities for the protection of the American public." Citizens Advisory Committee on the FDA, Report to the Secretary of Health, Education, and Welfare, H. R. Doc. No. 227, 84th Cong., 1st Sess., 53.

drugs, especially in the post marketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.[12] The agency's 2006 preamble represents a dramatic change in position. " (pp. 25-26) A shift in position that the Court believed did not merit deference. (p. 24)

Therefore FDA approval alone is not sufficient for Defendant's claim that its warning was adequate as a matter of law.

Three recent studies have reached similar conclusions. See FDA Science Board, Report of the Subcommittee on Science and Technology: FDA Science and Mission at Risk 2, 6 (2007), online at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf (all Internet materials as visited Feb. 23, 2009, and available in Clerk of Court's case file) ("[T]he Agencysuffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities"); National Academies, Institute of Medicine, The Future of Drug Safety: Promoting andProtecting the Health of the Public 193–194 (2007) ("The [FDA] lacks the resources needed to accomplish its large and complex mission . . . .There is widespread agreement that resources for postmarketing drugsafety work are especially inadequate and that resource limitationshave hobbled the agency's ability to improve and expand this essentialcomponent of its mission"); GAO, Drug Safety: Improvement Needed inFDA's Postmarket Decision-making and Oversight Process 5 (GAO–06–402, 2006), http://www.gao.gov/new.items/d06402.pdf ("FDA lacks a clear and effective process for making decisions about, and providingmanagement oversight of, postmarket safety issues"); see also House Committee on Oversight and Government Reform, Majority Staff Report, FDA Career Staff Objected to Agency Preemption Policies 4(2008) ("[T]he Office of Chief Counsel ignored the warnings from FDA scientists and career officials that the preemption language [of the 2006preamble] was based on erroneous assertions about the ability of thedrug approval process to ensure accurate and up-to-date drug labels").

[2] "See generally Brief for Former FDA Commissioners Drs. Donald Kennedy and David Kessler as *Amici Curiae;* see also Kessler & Vladeck, A Critical Examination of the FDA's Efforts To PreemptFailure-To-Warn Claims, 96 Geo. L. J. 461, 463 (2008); *Bates* v. *Dow Agrosciences LLC*, 544 U. S. 431, 451 (2005) (noting that state tort suits"can serve as a catalyst" by aiding in the exposure of new dangers andprompting a manufacturer or the federal agency to decide that a revised label is required).

III Argument

Defendant had repeatedly been warned by the FDA regarding its direct-to-consumer (DTC) advertising for Lipitor that was in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). (See Ex. A) In 2010 Pfizer was warned by the FDA for its failure to submit Adverse Drug Experience (ADE) reports to the FDA as required by 21 CFR 314.80c specifically listing Lipitor among the products. Pfizer failed to submit reports of adverse drug experiences to the FDA within the 15 calendar days as required by 21 CFR 314.80 c (1)(i). Delays in reporting adverse events related to Lipitor were 1141 and 1102 days. (See Ex. B)

In 2009 Pfizer was party to the largest health care fraud settlement in the history of the Justice Department. (See Ex. C) While the criminal and civil penalties in this case were related to Pfizer's promotion of FDA approved drugs for "off label" use, i.e. any use not specified in an application and approved by FDA, Justice Department officials recognized that when manufacturers undermine the FDA's rules, they interfere with a doctor's judgment and can put patient health at risk. (See Ex. C, Ex. D)

In September 2010 the Justice Department filed a Statement of Interest in the case United States of America ex rel, Dr. Jesse Polansky v. Pfizer, Inc. (EDNY 04-cv-0704). (See Ex. E) Dr. Polansky alleged that Pfizer sales representatives were instructed to promote Lipitor therapy for patients outside the risk categories

and cutpoints set forth in the National Cholesterol Education Program Guidelines and to minimize the side effects of the drug. According to National Health and Nutrition Examination Survey, the off-label use for Lipitor has increased from 9.4% in 2001 to 24.7% in 2007. According to data from Pfizer's own websites, Defendant spends an average of $193,000 per quarter in payments to physicians in Maryland alone. While this does not suggest any professional wrong doing on the part of the physicians, "the pharmaceutical industry would not employ the army of sales representatives who promote their products if these sales efforts had no effect on physician practices." (See Ex. E, p. 9)

The Defendant is considered an expert in its field, and as such it has a continuing duty to keep abreast of knowledge regarding its products and take all reasonable steps to update medical professionals on their potential adverse effects. Information from the FDA and the Department of Justice concludes the Defendant used its position as expert to expand sales rather than safeguard the health of patients. This resulted in injury to the Plaintiff.

Plaintiff has stated a claim upon which relief can be granted and Defendant's label was not adequate as a matter of law. The Defendant's arguments fail because,

1. while the Plaintiff's complaint may have been incomplete, implicit within the facts presented is a claim of failure to warn by the Defendant.; and

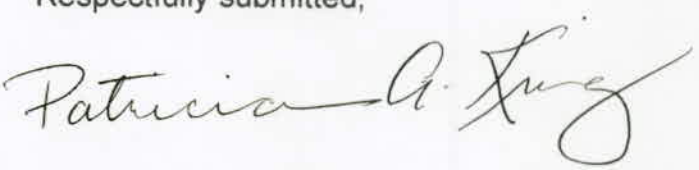
2. the recent U.S. Supreme Court decision Wyeth v. Levine, 555 U.S. _____ (2009) permits a Plaintiff to challenge the adequacy of Defendant's warning label even when approved by the FDA.

IV Conclusion

Therefore Defendant's Motion for Dismissal with prejudice should not be granted.

If the Court nevertheless believes that Plaintiff's complaint does not adequately state a claim upon which relief can be granted, then her complaint should be dismissed but without prejudice.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2011, I filed the foregoing Response to Motion to Dismiss with the Clerk of the Court and served a copy of the foregoing upon the Defendant/Attorneys for the Defendant Pfizer, Inc. by U.S. First Class Mail, certified, postage prepaid:

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